FLUIDIC COMPRESSION DEVICE ADAPTED TO ACCOMMODATE AN EXTERNAL FIXATION DEVICE

RELATED APPLICATIONS

This application claims the benefit under 35 U.S.C. §119(e) of U.S. Provisional Patent Application No. 60/396,523 entitled "Fluodic Compression Apparatus Accommodating An External Fixation Device" filed July 17, 2002.

TECHNICAL FIELD OF THE INVENTION

This invention relates generally to medical devices and, more particularly, to a fluidic compression device adapted to accommodate an external fixation device.

BACKGROUND

Fluidic compression devices may be used to prevent or treat deep venous thrombosis (DVT) (i.e. blood clots in the legs), pulmonary embolism (PE) (i.e. blood clots in the lungs), or other circulation problems. For example, such problems may arise following surgery or other trauma to a limb. If such problems are not prevented or are left untreated the consequences are potentially fatal. Using a fluidic compression device that has been filled with air, water, or another suitable fluid, pressure may be periodically, cyclically, or otherwise intermittently applied to a portion of a user's body, such as the ankle or another portion of the leg or other limb, to increase venous blood flow and thereby prevent or treat DVT, PE, or other circulation problems.

SUMMARY OF THE INVENTION

According to the present invention, certain disadvantages and problems associated with previous fluidic compression devices may be reduced or eliminated.

In certain embodiments, a fluidic compression device adapted to accommodate an external fixation device includes at least one fluid-impermeable bladder adapted to contain a fluid and at least one region adapted to receive and accommodate one or more external portions of an external fixation device. The fluidic compression device is adapted to be positioned about a portion of a user's body such that an opening formed within the region receives and accommodates one or more external portions of the external fixation device. The fluidic compression device is further adapted to apply intermittent compression to the portion of the user's body according to intermittent increases and decreases in fluid pressure in the bladder while the device is positioned about the portion of the user's body and is accommodating the external fixation device.

In other embodiments, a method for manufacturing a fluidic compression device adapted to accommodate an external fixation device includes providing at least one fluid-impermeable bladder adapted to contain a fluid and providing at least one region adapted to receive and accommodate one or more external portions of an external fixation device. The fluidic compression device is adapted to be positioned about a portion of a user's body such that an opening formed within the region receives and accommodates the one or more external portions of the external fixation device. The fluidic compression device is further adapted to apply intermittent compression to the portion of the user's body according to intermittent increases and decreases in fluid pressure in the bladder while the device is positioned about the portion of the user's body and is accommodating the external fixation device.

In other embodiments, a method for preventing or treating circulation problems includes positioning a fluidic compression device about a portion of a user's body such that at least one opening formed in a region of the device receives and accommodates one or more external portions of an external fixation device. The method further includes at least partially filling at least one fluid-impermeable bladder of the fluidic compression device with fluid. The method further includes intermittently increasing and decreasing fluid pressure within the bladder to apply

intermittent compression to the portion of the user's body while the fluidic compression device is positioned about the portion of the user's body and is accommodating the external fixation device, the intermittent compression facilitating prevention or treatment of circulation problems associated with the portion of the user's body.

Particular embodiments of the present invention may provide one or more technical advantages. Certain embodiments provide a fluidic compression device that accommodates an external fixation device that is already in place with respect to a portion of a user's body, such as the user's ankle or another portion of the user's leg or other limb. Certain embodiments allow suitable pressure to be periodically, cyclically, or otherwise intermittently applied to the portion of the user's body to prevent or treat DVT, PE, or other circulation problems. For example, such problems often arise following surgery or other significant trauma to the portion of the user's body due to post-operative immobilization, including external fixation, and concomitant loss of venous pump function, which may allow blood clots to form. It has been approximated that forty percent of users receive external fixation devices following limb surgery. However, despite the risks of DVT, PE, or other circulation problems and the potentially fatal consequences of such problems, previous fluidic compression devices have not accommodated external fixation devices, leaving a significant portion of the at risk population unserved. Certain embodiments may be readily customized to accommodate a particular external fixation device. Certain embodiments allow customization to be performed without jeopardizing the integrity of the bladder within the device containing the fluid. Certain embodiments accommodate a variety of external fixation devices, and preferably any suitable external fixation device, with or without customization.

Certain embodiments may provide all, some, or none of these technical advantages. Certain embodiments may provide one or more other technical advantages, one or more of which may be readily apparent to those skilled in the art from the figures, description, and claims included herein.

BRIEF DESCRIPTION OF THE DRAWINGS

To provide a more complete understanding of the present invention and the features and advantages thereof, reference is made to the following description taken in conjunction with the accompanying drawings, in which:

FIGURE 1 illustrates an example fluidic compression device in use in combination with an external fixation device;

FIGURE 2 illustrates a side view of an example fluidic compression device;

FIGURE 3 illustrates a side view of an example fluidic compression device including at least one fluid-impermeable bladder;

FIGURE 4 illustrates a side view of a portion of an example fluidic compression device including a sealed cut line;

FIGURE 5 illustrates an example connector;

FIGURE 6 illustrates a cross-sectional view of an example fluidic compression device;

FIGURES 7A and 7B illustrate side views of alternative embodiments of a strap of an example fluidic compression device; and

FIGURE 8 illustrates an example method for preventing or treating circulation problems using an example fluidic compression device.

DESCRIPTION OF EXAMPLE EMBODIMENTS

FIGURE 1 illustrates an example fluidic compression device 10 in use in combination with an external fixation device 5 on a user's foot and ankle. In general, device 10 may be used to periodically, cyclically, or otherwise intermittently apply pressure to a portion of a user's body while accommodating an external fixation device 5 already in place on the user's body to prevent or treat DVT, PE, or other circulation problems. Although device 10 for fluidic compression of portions of a user's foot and ankle is illustrated by way of example, the present invention contemplates device 10 for fluidic compression of any suitable portion of the user's body while accommodating an external fixation device 5. Furthermore, although the use of device 10 in association with an external fixation device 5 is illustrated, the present invention contemplates device 10 being used to benefit the user whether or not an external fixation device 5 is also being used. The ability to accommodate an external fixation device 5 may provide an important technical advantage. In certain embodiments, device 10 may be readily customized, in the manner described below for example, to accommodate a particular external fixation device 5. In certain embodiments, device 10 may accommodate a variety of external fixation devices 5, and preferably any suitable external fixation device 5, with or without customization.

Device 10 may be constructed using a soft, foldable, and flexible external woven material that at least substantially covers a soft, foldable, and flexible internal foam material. These materials may encompass one or more silastic or other fluid-impermeable bladders that may be at least partially filled with fluid during use. As used in this document, the term "fluidic" is meant to encompass use of any suitable fluid within device 10, such as air, water, or any other fluid. The pressure of the fluid contained in the bladder may be cycled to apply compression to a portion of the user's body, such as an ankle or another portion of the leg or other limb, to increase venous blood flow and thereby prevent or treat DVT, PE, or other circulation problems. In a particular embodiment, when the bladder is at least partially filled with fluid, device 10 may apply approximately one hundred thirty millimeters of mercury (130mm Hg) pressure to approximately one hundred eighty millimeters of mercury (180mm Hg) pressure to the portion of the user's body being compressed. Although an example fluid pressure range is provided, the present invention contemplates any appropriate

pressure and pressure range according to particular needs and circumstances. For example, the fluid pressure and fluid pressure range for treatment of a foot and ankle may be different than the fluid pressure and fluid pressure range for treatment of a leg, arm, or other limb.

In certain embodiments, fluidic compression device 10 includes a circumferential portion 16 that wraps around portions of the user's foot and ankle. Device 10 may also include a heel strap portion 24 that wraps around portions of the user's heel. Device 10 may include one or more openings 35 each adapted to receive and accommodate one or more corresponding external portions of external fixation device 5. As described more fully below, in certain embodiments each such opening 35 may be cut within a sealed region to customize device 10 for a particular external fixation device 5. In certain embodiments, openings 35 accommodate a variety of external fixation devices 5, and preferably any suitable external fixation device 5, with or without customization.

FIGURE 2 illustrates a side view of an example fluidic compression device 10. In certain embodiments, fluidic compression device 10 includes a main body 12 and an edge 14 that substantially surrounds main body 12. A cross-sectional view of edge 14 and main body 12 is discussed below with reference to FIGURE 6. Circumferential portion 16 may include a strap 18 used to couple an elongated lateral portion 20 of circumferential portion 16 to a medial portion 22 of circumferential portion 16 to secure device 10 around portions of the user's foot and ankle. In certain embodiments, strap 18 may include two separate portions 30a and 30b allowing strap 18 to be fitted around a variety of external fixation devices 5, and preferably any suitable external fixation device 5, which may be passed through strap 18 within an opening 32. Alternative embodiments of strap 18 are discussed below with reference to FIGURES 7A and 7B. Heel strap portion 24 may include a strap 26 used to couple an elongated end portion 28 of heel strap portion 24 to circumferential portion 16 to secure device 10 around portions of the user's heel and foot.

Straps 18 and 26 are preferably, but need not be, substantially inelastic so as to provide limited lengthening or widening under stress. Straps 18 and 26 may, with corresponding locations of elongated lateral portion 20 of circumferential portion 16 and elongated end portion 28 of heel strap portion 24, respectively, support any

appropriate fasteners. For example, in certain embodiments, straps 18 and 26 support VELCRO or another suitable hook and loop fastener to secure straps 18 and 26 to corresponding locations on elongated lateral portion 20 of circumferential portion 16 and elongated end portion 28 of heel strap portion 24, respectively. In a particular embodiment, VELCRO 3600 or VELCRO 3800 may be used. However, any suitable fasteners, such as snaps, buttons, or other fasteners, may be used according to particular needs.

Device 10 may include a connector 34 for coupling device 10 to a fluid source and for receiving air, water, or another suitable fluid from the fluid source to at least partially fill the bladder of device 10 and increase the fluid pressure within the bladder as desired. Connector 34 may also be used to release fluid from the bladder to decrease the fluid pressure within the bladder as desired. Through intermittent increases and decreases in the fluid pressure within the bladder, intermittent compression of the targeted portion of the user's body is achieved. An example connector 34 is described in more detail below with reference to FIGURE 5.

In certain embodiments, as described above, device 10 is customizable to accommodate a particular external fixation device 5 using one or more openings 35. Device 10 may include pre-formed holes 38 that are preferably sized to accommodate a cutting device. The cutting device may be inserted in a hole 38 and then used to cut through device 10 to form an opening 35 sufficient to receive and accommodate one or more corresponding external portions of the particular external fixation device 5. As discussed below with reference to FIGURE 4, in certain embodiments, a visible cut line may be provided on device 10 to guide such cutting. Although four pre-formed holes 38 and associated openings 35 in particular locations are illustrated by way of example, the present invention contemplates any suitable number of holes 38 and associated openings 35 in any suitable locations.

FIGURE 3 illustrates a side view of an example fluidic compression device 10 including a fluid-impermeable bladder 40. One or more such bladders 40 may be provided within device 10. In certain embodiments, fluidic compression device 10 may include one or more seals 44, which define one or more sealed regions 42. Seals 44 may comprise hermetic seals, radio frequency (RF) seals, or any other appropriate seal. Double seals 44 may be provided for increased durability and reliability.

Device 10 may also include stitching 46 near each seal 44 within the corresponding sealed region 42 to provide additional durability and reliability. Stitching 46 may also provide a safety margin during cutting of an opening 35. Stitching 46, in combination with seals 44, may help to ensure that device 10 can be cut as necessary to accommodate any suitable external fixation device 5 without comprising the integrity of bladder 40. Seals 44 and stitching 46 may therefore serve as an "integrity buffer" for bladder 40. In certain embodiments, bladder 40 provides a single fluid-impermeable chamber, shaped according to the configuration of sealed regions 42, which substantially fills the surrounding regions of device 10. However, as described above, device 10 may include one or more bladders 40 providing one or more such chambers.

FIGURE 4 illustrates a side view of a portion of an example fluidic compression device 10 including a sealed cut line 48. As discussed above, a user may cut through device 10 within a sealed region 42 to form an opening 35 in device 10 sufficient to receive one or more external portions of external fixation device 5. In certain embodiments, cut line 48 may be indicated visibly on device 10, such as by a solid or dotted line printed on device 10, and may also be perforated to allow cutting to be performed more easily. Cut line 48 may be used to guide a user in cutting within sealed region 42 such that bladder 40 is not perforated during cutting.

FIGURE 5 illustrates an example connector 34. In certain embodiments, connector 34 may be a graduated, multi-circumference connector for coupling to an appropriate fluid source and for receiving air, water, or another suitable fluid from the fluid source to at least partially fill bladder 40. For example, connector 34 may couple to a hose to receive air from a pneumatic compression pump. Connector 34 may also be operable to release fluid from bladder 40. In a particular embodiment, connector 34 may include a valve to prevent fluid pressure from unintentionally escaping from bladder 40 after bladder 40 is filled with an appropriate fluid. Through intermittent increases and decreases in the fluid pressure within bladder 40, intermittent compression of the targeted portion of the user's body is achieved. A flange 36 may be used to support connector 34 and prevent leakage of fluid from bladder 40. In certain embodiments, flange 36 may be formed from a hardened silastic, plastic, or other suitable material and may be formed in a "stair-stepped"

configuration. Flange 36 may be sealed in two locations for improved durability and stronger adherence to main body portion 12 during installation and use.

FIGURE 6 illustrates a cross-sectional view of an example fluidic compression device 10. As described above, device 10, including main body 12 and edge 14, may be constructed using a soft, foldable, and flexible external woven material that at least substantially covers a soft, foldable, and flexible internal foam material. In main body 12, these materials encompass one or more silastic or other fluid-impermeable bladders 40 that may be at least partially filled with fluid during use. FIGURE 6 shows bladders 40 in an inflated state. In a particular embodiment, the external woven material of main body 12 may be sealed, bonded, stitched, or otherwise coupled to the internal foam and the internal foam may be sealed, bonded, stitched, or otherwise coupled to the one or more bladders 40.

A combination of the same external woven material and internal foam material used to form main body 12 may also be configured to form a "rolled" or otherwise rounded edge 14 to improve comfort and to prevent or reduce problems such as dermal ulcerations. For example, the external woven material may be rolled around the internal foam material and sealed, bonded, stitched, or otherwise coupled to main body portion 12. In a particular embodiment, the external woven material of edge 14 may be sealed, bonded, stitched, or otherwise coupled to the internal foam material. In FIGURE 6, the external woven material of main body 12 and rounded edge 14 is indicated using diagonal stripes and the internal foam material is indicated using stippling.

FIGURES 7A and 7B illustrate alternative example straps 18. In certain embodiments, as shown in FIGURE 7A, strap 18 may be provided without any cutouts or openings 32. In another embodiment, as shown in FIGURE 7B, strap 18 may be provided with an enclosed opening 32 formed in strap 18, allowing strap 18 to be fitted around a variety of external fixation devices 5, and preferably any suitable external fixation device 5, which may pass through strap 18 within opening 32.

FIGURE 8 illustrates an example method for using device 10 to prevent or treat DVT, PE, or other circulation problems. The example method begins at step 102, when one or more openings 35 are cut or otherwise formed in device 10 to accommodate one or more external portions of an external fixation device 5. As

described above, in certain embodiments, device 10 may be customized in this manner to accommodate any suitable external fixation device 5. At step 104, device 10 is placed over the portion of the user's body to receive treatment such that each opening 35 in device 10 receives and accommodates the one or more corresponding external portions of external fixation device 5. At step 106, one or more straps 18, 26 may be used to couple together opposing portions of device 10 to secure the device around the portion of the user's body. At step 108, one or more fluid-impermeable bladders 40 are at least partially filled with an appropriate fluid, such as air, water, or any other fluid. At step 110, device 10 is used to apply intermittent compression to the portion of the user's body in response to corresponding intermittent increases and decreases in fluid pressure in bladder 40. Such compression may be periodically, cyclically, or otherwise intermittently applied.

Although an example method is illustrated, the present invention contemplates two or more steps taking place substantially simultaneously or in a different order. In addition, the present invention contemplates using methods with additional steps, fewer steps, or different steps, so long as the methods remain appropriate for using a fluidic compression device 10 adapted to accommodate an external fixation device 5 to prevent or treat a user's circulation problems.

Furthermore, although the present invention has been described with several embodiments, a multitude of changes, substitutions, variations, alterations, and modifications may be suggested to one skilled in the art, and it is intended that the invention encompass all such changes, substitutions, variations, alterations, and modifications as fall within the spirit and scope of the appended claims.